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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,854	03/12/2001	Albert J. Wong	WON01-NP003	1297

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EXAMINER	
CHEU, CHANGHWA J	

ART UNIT	PAPER NUMBER
1641	9

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/803,854	WONG ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *12-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I, claims 1-11 in Paper No. 8 is acknowledged. Non-elected group II, claims 12-20, are thus withdrawn from further consideration.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, "EGFRvIII" is vague and indefinite. It is suggested that applicant spell out the whole name of EGFRvIII.

With respect to claim 1, "ELISA" needs to spell out.

With respect to claim 2, "CSF" needs to spell out.

With respect to claim 6, line 6, "EL:SA" is vague and indefinite. Applicant needs to correct the abbreviation.

With respect to claim 6, it is unclear to one skilled in the art as to how to select a mammal for anticancer therapies. It is unclear about the relationship between the quantifying EGFRvIII from the mammals having cancer and the EGF-directed anticancer therapies.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 3, 5, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wikstrand et al. (Cancer Res. 1997 57: 4130-4140) in view of Morgan et al.. (US 5084396)

Wikstrand et al. teach assessing the qualitative distribution and quantitative expression of the EGFRvIII from neoplastic tissue samples, i.e. non-small cell lung carcinoma, and breast carcinoma. (See abstract, Methods, and Table 3) The samples are from both athymic mice and rats xenografted with the EGFRvIII transfected cell lines. (See Method) The quantification of the EGFRvIII is conducted by use of EGFRvIII specific monoclonal antibody L8A4. (See abstract and Method) Although Wikstrand et al. do not explicitly disclose using ELISA for measuring the EGFRvIII, Morgan et al. disclose that it is considered a common practice for incorporating ELISA assay in the art once the specific monoclonal antibody is available. (Col. 5, line 55-60) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have

provided the assay of Wikstrand et al. with the ELISA assay as taught by Morgan et al, since it is a common practice in the art for one to measure the target protein once the specific antibody, i.e. L8A4, is available.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moscatello et al. (Cancer Res. 1997 57: 1419-1424) in view of Morgan et al..

Moscaetllo et al. disclose that a EGFRvIII derived polypeptides from the junction of EGFRvIII could serve as a bais for antitumor vaccine. (See abstract, Method, Figure 4) Moscaetllo et al. show that mice with preimmunization with the EGFRvIII polypeptides substantially tumor formation. Supra. However, Moscatello et al. use Western blot instead of ELISA for analysis of tumor tissue sample. Nevertheless, Morgan et al. disclose that it is considered a common practice for incorporating ELISA assay in the art once the specific monoclonal antibody is available. (Col. 5, line 55-60) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the assay of Moscaetllo et al. with the ELISA assay as taught by Morgan et al to develop anticancer therapies, since it is a common practice in the art for one to measure the target protein once the specific antibody, i.e. L8A4, is available.

Allowable Subject Matter

8. Claim 8 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

9. Claims 2, 4, 7, 8, 10 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

10. The following is an examiner's statement of reasons for allowance: no prior art teaches or suggests cancer diagnosis by using an ELISA assay to detect EGFRvIII from a mammal

biological samples, including urine, plasma, serum, amniotic fluid, breast secretions, lung sputum or tumor cell extracts. The closest prior art is Wikstrand et al. where Wikstrand reference only capable of using *biopsy tissue* samples from mammals, not the samples recited in this application. The instant invention is practical and more convenient for clinical applications.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-746-9434.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu
Examiner
Art Unit 1641

November 9, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
11/10/03